

US3492237 (Prod: UIC Project WISH CRS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:30:15

All time stamps listed in this document are displayed in GMT

US3492237

Form: Participant Creation

Generated On: 26 Nov 2020 09:30:15

[Participant ID](#)

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[mRNA-1273-P301 Completion Guidelines](#)

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:30:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:30:15

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

Condition	ASTHMA-MILD
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

Condition	GASTRO-ESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:50 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:50
Height (<i>xxx.x</i>)	170 cm
Weight (<i>xxx.x</i>)	103 kg
BMI (<i>xxx.x</i>)	35.64014 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify

AIRLINE EMPLOYEE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

What was the date of randomization? (dd MMM yyyy) 22 SEP 2020

What was the participant's randomization number? 115295

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:50
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:52
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	22 SEP 2020
What was the treatment time? (00:00-23:59)	16:42 (24 HR)
Treatment Date and Time (derived)	22 SEP 2020 16:42
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

22 SEP 2020

Collection time (*00:00-23:59*)

15:58 (24 HR)

Collection date and time (derived)

22 SEP 2020 15:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:30:15

Collection date (<i>dd MMM yyyy</i>)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:05	22 SEP 2020 16:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

22 SEP 2020 17:03

PC Open Date & Time

22 SEP 2020 17:02

PC Close Date & Time

22 SEP 2020 19:32

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 22 SEP 2020 20:27

PC Close Date & Time 23 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

23 SEP 2020 20:44

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

24 SEP 2020 22:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

25 SEP 2020 22:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

101.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

26 SEP 2020 19:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.6 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	27 SEP 2020 12:33
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	28 SEP 2020 21:14
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 8

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	100.7 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 17:33
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 9

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 SEP 2020 12:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:04

PC Open Date & Time

22 SEP 2020 17:02

PC Close Date & Time

22 SEP 2020 19:32

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 20:46

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 22:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 22:38

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 19:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:33

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 21:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 17:05
PC Open Date & Time	22 SEP 2020 17:02
PC Close Date & Time	22 SEP 2020 19:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 20:27

PC Close Date & Time

23 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	23 SEP 2020 20:47
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	24 SEP 2020 22:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	25 SEP 2020 22:39
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	26 SEP 2020 19:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	27 SEP 2020 12:35
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

Yes ☐	
PC Time stamp	28 SEP 2020 21:16
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 29 SEP 2020 17:34

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 30 SEP 2020 12:10

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 29 SEP 2020 17:35

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 30 SEP 2020 12:11

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

01 OCT 2020 15:10

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 02 OCT 2020 12:36

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 04 OCT 2020 16:45

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 06 OCT 2020 16:45

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 17:15

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:35

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:33

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 10 OCT 2020 12:00

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity not requiring medical attention ☐

Prevents daily activity and requires medical attention ☐

PC Open Date & Time	29 SEP 2020 12:00

PC Close Date & Time	30 SEP 2020 11:59

PC Time stamp	29 SEP 2020 17:35

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

PC Time stamp 30 SEP 2020 12:11

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity not requiring medical attention ☐

Prevents daily activity and requires medical attention ☐

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

PC Time stamp 01 OCT 2020 15:11

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

PC Time stamp 02 OCT 2020 12:36

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

PC Time stamp

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time	04 OCT 2020 12:00

PC Close Date & Time	05 OCT 2020 11:59

PC Time stamp	04 OCT 2020 16:45

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

PC Time stamp

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

PC Time stamp 06 OCT 2020 16:45

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 17:35
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 SEP 2020 12:11
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 15:11
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 OCT 2020 12:36
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 OCT 2020 16:46
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 15

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp

06 OCT 2020 16:45

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 OCT 2020 12:35
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 12:34
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 OCT 2020 12:00
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

DIAGNOSED WITH SARS-COV2

ON 28SEP2020, IN ILLNESS

If Contact Not Made, please provide Comments

TRACK

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☐

Folder OID	VISIT2

US3492237

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492237

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

Was study treatment given? Yes ☐
No ☐

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3492237

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	

Collection time (<i>00:00-23:59</i>)	

Collection date and time (derived)	

US3492237

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:30:15

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	14:55 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 14:55
Temperature (<i>xxx.x</i>)	96.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 NOV 2020
Collection time (<i>00:00-23:59</i>)	15:05 (24 HR)
Collection date and time (derived)	23 NOV 2020 15:05

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 341

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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10 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

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11 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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21 APR 2022 00:01

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25 APR 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

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02 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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09 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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26 MAY 2022 00:01

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30 MAY 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3492237

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492237

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

Date of Contact	27 SEP 2020
Time of Contact	12:00
Date and Time of Contact (derived)	27 SEP 2020 12:00
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	332 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	336 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	340 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	344 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.5 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	348 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	352 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	356 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	360 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	364 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	368 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	372 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	376 of 2167	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	380 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	384 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	388 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	392 of 2167	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:30:15

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	22 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

If Yes to either Did subject require any of the following:

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:30:15

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:30:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 SEP 2020
Day 5	Yes	2 OCT 2020
Day 7	Yes	4 OCT 2020
Day 9	Yes	6 OCT 2020
Day 14	Yes	11 OCT 2020
Day 21	Yes	18 OCT 2020
Day 28	Yes	26 OCT 2020

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:13
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	100.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492237

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 15:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3492237

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:30:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

AEID	USA-US101-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19 INFECTION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	22 SEP 2020
Start time (00:00-23:59)	14:00 (24 HR)
AE start date and time (derived)	22 SEP 2020 14:00
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	9 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

PARTICIPANT CALLED STUDY STAFF ON 27SEP2020 TO REPORT THAT HE HAS BEEN HAVING SYMPTOMS OF A RESPIRATORY INFECTION. HE RECEIVED HIS FIRST DOSE OF IP ON 9/22, WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. HIS TEMP THAT DAY WAS ABOUT 99. THE FOLLOWING DAY HE DEVELOPED HEADACHE, CONTINUED WITH FEVER TO 101 AND CHILLS. YESTERDAY 9/26, HE DEVELOPED A PRODUCTIVE COUGH, SCANTY CLEAR SPUTUM. HE HAS BEEN TAKING NAPROSYN DAILY SINCE THE FEVERS BEGAN WITH SOME RELIEF. NO LOCALIZED INJECTION SITE PAIN. NO SOB. HE HAS ASTHMA AND CONTINUES TO USE HIS INHALER. NO KNOWN SICK CONTACTS ALTHOUGH HE REPORTS HIS WIFE IS HAVING A FLARE OF FIBROMYALGIA AND HAS A LOW GRADE FEVER.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:30:15

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	ADVAIR
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	500-50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☒ No ☐
Indication	ASTHMA
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	FLUTICASONE
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	100
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	AZELASTINE
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☒ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☒
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐

If route of administration is Other, specify _____

Start date (dd MMM yyyy) _____

Start date completely unknown True

Ongoing? Yes ☒

No ☐

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes ☐

No ☒

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802 ☐

803 ☐

804 ☒

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	TYLENOL
Prophylaxis	Yes ☒ No ☐
Indication	FEVER ASSOCIATED WITH COVID INFECTION
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	NAPROXEN
Prophylaxis	Yes ☒ No ☐
Indication	MYALGIAS, ARTHRALGIAS ASSOCIATED WITH COVID INFECTION
Dose per administration	220
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	2ND DOSE OF SHINGLES VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNK
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	COUGH FROM COVID
Dose per administration	250
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492237

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:30:15

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:30:15

Date of dosing discontinuation (dd MMM yyyy)

28 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3492237

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:30:15

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:30:15

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:30:15

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/NOV/2020 00:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:30:15

SAEID	USA-US101-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/NOV/2020 13:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3492237 (Prod: UIC Project WISH CRS)

US3492237

Form: Participant Creation

Generated On: 26 Nov 2020 09:30:15

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3492237'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Sep 2020 20:10:25

US3492237

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Sep 2020 20:10:26

US3492237

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	22 Sep 2020 21:05:41

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Sep 2020 20:10:27

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Age](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '60'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:30:15

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:05:55

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) [REDACTED]	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:06:17

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Sep 2020 20:10:26

US3492237

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:30:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:30:15

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:30:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:41:18
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:07:13

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:42:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:42:51
Data point term sent to Coder	System	01 Nov 2020 21:42:37
User entered 'Asthma-mild'	Andrea Wendrow (b) (4) (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1966'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:09
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1966'	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1966'	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:30:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:42:09

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:44:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:44:52
Data point term sent to Coder	System	01 Nov 2020 21:43:39
User entered 'Gastro-esophageal reflux disease'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:42:47
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:30:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:42:47

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 21:45:52
Data point term sent to Coder	System	01 Nov 2020 21:44:40
User entered 'Allergic Rhinitis'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	01 Nov 2020 21:44:36
	(b) (4)	

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:30:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:44:36

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:50'	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '170' cm	(b) (4), (b) (6)	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '103' kg	(b) (4), (b) (6)	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '35.64014'	System	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	22 Sep 2020 21:07:54
DataPoint set to visible.	System	22 Sep 2020 21:06:22

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6) [REDACTED]	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:07:54

US3492237

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:08:04

US3492237

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:08:04

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

[Specify](#)

Audit	User	Time (GMT)
User entered 'airline employee'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:30:15

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:08:33

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	22 Sep 2020 21:09:00

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '115295'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Sep 2020 21:00:37

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	22 Sep 2020 21:09:35

US3492237

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:30:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:09:35
DataPoint set to visible.	System	22 Sep 2020 21:06:17

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) [REDACTED]	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:50'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '125'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:30:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:51:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:51:40
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:10:23
User entered empty.	(b) (4), (b) (6) (b) (4)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:52' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:52'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Gizelle Alvarez	(b) (4)	22 Sep 2020 21:51:40
Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	22 Sep 2020 21:51:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:51:40
User entered empty.	System	22 Sep 2020 21:10:23

US3492237

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:10:57

US3492237

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:10:57

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:42'	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:42'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Gizelle Alvarez (b) (4) (b) (4)	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:30:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 21:49:22

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:58'	(b) (4), (b) (6)	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 15:58'	System	22 Sep 2020 21:27:31

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:30:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:30:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:30:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:30:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '16:05'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:30:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:30:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:30:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:30:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:30:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 21:28:24

US3492237

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:28:30

US3492237

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:28:30

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered 'Yes (Y)'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:02:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered '97.9'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered 'No (N)'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:03:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'cf52e7df-f643-4de8-9584-7ffb5e75633a'	System	22 Sep 2020 22:03:54
User entered '22 Sep 2020 17:03'	System	22 Sep 2020 22:03:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:43:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered 'Yes (Y)'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:41', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered '97.6'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:47', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered 'No (N)'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:44:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'f7f445f6-772a-4344-a4bd-7919b6b67453'	System	24 Sep 2020 01:45:01
User entered '23 Sep 2020 20:44'	System	24 Sep 2020 01:45:01

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered 'Yes (Y)'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:35', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered '99.5'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:43:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered 'No (N)'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'bb1e124d-7648-46ba-ade9-d209194b4600'	System	25 Sep 2020 03:44:09
User entered '24 Sep 2020 22:44'	System	25 Sep 2020 03:44:09

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered 'Yes (Y)'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc' User entered '98.1'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered 'No (N)'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:37:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7acfbde5-730b-4c1b-bfd2-cbbc7297becc'	System	26 Sep 2020 03:38:00
User entered '25 Sep 2020 22:37'	System	26 Sep 2020 03:38:00

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T18:59:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered 'Yes (Y)'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered '101.0'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered 'No (N)'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5397d17f-4e8d-4c4a-9322-5b37df25c678'	System	27 Sep 2020 00:00:26
User entered '26 Sep 2020 19:00'	System	27 Sep 2020 00:00:26

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:31:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered 'Yes (Y)'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:31:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '99.6'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered 'Yes (Y)'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PAIN TYLENOL TO TREAT FEVER' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 07:33:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '1'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:32:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca' User entered '0'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '73b8495a-f4db-4819-b13d-e9df944b5dca'	System	27 Sep 2020 17:33:05
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered 'Yes (Y)'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '99.1'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered 'Yes (Y)'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:52:30
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Sep 2020 02:14:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '1'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:13:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '0'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd5da1ff8-9eed-489d-a21a-e58e3759e7f6'	System	29 Sep 2020 02:14:31
User entered '28 Sep 2020 21:14'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 17:33:05
User entered 'Day 8'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered 'Yes (Y)'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '100.7'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered 'Yes (Y)'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:52:36
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Andrea Wendrow (b) (4)	01 Oct 2020 21:18:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Sep 2020 22:33:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '1'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '0'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:33:50', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '5d8e8144-66c6-4341-a5a5-4b219e4435f0'	System	29 Sep 2020 22:33:54
User entered '29 Sep 2020 17:33'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:14:31
User entered 'Day 9'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered 'Yes (Y)'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered '98.7'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered 'No (N)'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9a96acb4-c894-4a6c-889b-38c93520becf'	System	30 Sep 2020 17:10:46
User entered '30 Sep 2020 12:10'	System	30 Sep 2020 17:10:46

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'None (1)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'No (N)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'No (N)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered 'None (1)'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '22d7c567-708c-4282-846a-3d065345bdd8'	System	22 Sep 2020 22:04:37
User entered '22 Sep 2020 17:04'	System	22 Sep 2020 22:04:37

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:45:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:45:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'No (N)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'No (N)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered 'None (1)'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9bb89e9a-acef-45df-8aec-14b1aebd4176'	System	24 Sep 2020 01:46:33
User entered '23 Sep 2020 20:46'	System	24 Sep 2020 01:46:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'None (1)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:18', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'No (N)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'No (N)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered 'None (1)'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '85674d51-9a16-4aa5-ae49-5acfb330d920'	System	25 Sep 2020 03:44:44
User entered '24 Sep 2020 22:44'	System	25 Sep 2020 03:44:44

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'None (1)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'No (N)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:18', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'No (N)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered 'None (1)'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b42a28a4-6adf-4b62-aec4-be5ef0724ee2'	System	26 Sep 2020 03:38:33
User entered '25 Sep 2020 22:38'	System	26 Sep 2020 03:38:33

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'None (1)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'No (N)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:00:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'No (N)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered 'None (1)'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:05', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a69c8a71-5d99-4189-8a84-d4f03e378851'	System	27 Sep 2020 00:01:11
User entered '26 Sep 2020 19:01'	System	27 Sep 2020 00:01:11

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'None (1)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'No (N)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'No (N)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered 'None (1)'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:31', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a9084c10-7ed8-4c9f-951c-fd3ebfff5e90'	System	27 Sep 2020 17:33:35
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 17:33:35

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:31', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'None (1)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:34', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'No (N)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'No (N)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered 'None (1)'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eba24a1a-6e29-425b-8fc2-859dde6957a5'	System	29 Sep 2020 02:14:49
User entered '28 Sep 2020 21:14'	System	29 Sep 2020 02:14:49

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:04:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:04', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:11', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:13', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'None (0)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:23', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered 'No (N)'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-22T17:05:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '807e0443-6438-47ba-a2fc-65431e618f3d'	System	22 Sep 2020 22:05:32
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 22:05:32

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:02'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 19:32'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 20:27'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 2'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:44', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:46:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:10', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:12', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'None (0)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered 'No (N)'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-23T20:47:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '64c5bebf-387b-4c02-902c-c7d72d3e4bca'	System	24 Sep 2020 01:47:25
User entered '23 Sep 2020 20:47'	System	24 Sep 2020 01:47:25

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 3'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:44:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'Some interference with activity (2)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:21', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'None (0)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:42', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered 'No (N)'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-24T22:45:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'ab524855-ddf7-49c0-9c40-eba719d6f344'	System	25 Sep 2020 03:45:57
User entered '24 Sep 2020 22:45'	System	25 Sep 2020 03:45:57

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 4'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:40', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'None (0)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:38:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'None (0)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e' User entered 'None (0)'	System	26 Sep 2020 03:39:26
	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'None (0)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:13', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered 'No (N)'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-25T22:39:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '36263254-f41c-49e9-9ff2-e3a39295982e'	System	26 Sep 2020 03:39:26
User entered '25 Sep 2020 22:39'	System	26 Sep 2020 03:39:26

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 5'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:01:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'None (0)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:29', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:36', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered 'No (N)'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-26T19:02:41', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '68a54175-b01d-4162-998a-96e1afbf6dda'	System	27 Sep 2020 00:02:47
User entered '26 Sep 2020 19:02'	System	27 Sep 2020 00:02:47

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 6'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:33:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:19', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:45', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'None (0)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:34:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:35:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered 'No (N)'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-27T12:35:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '399cecfb-d7a4-4e40-b3f2-2d54d5305291'	System	27 Sep 2020 17:35:49
User entered '27 Sep 2020 12:35'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 21:49:22
User entered 'Day 7'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:14:59', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:15:05', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:15:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'None (0)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'None (0)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'None (0)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:38', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:43', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered 'No (N)'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-28T21:16:46', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'b4f78b8a-5940-4bfa-b7d0-159f9c3d88fe'	System	29 Sep 2020 02:16:49
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 21:49:22

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:34:52', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '606ed0b5-fa94-4615-a254-14cf4ee10388'	System	29 Sep 2020 22:34:59
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:34:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:34:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '606ed0b5-fa94-4615-a254-14cf4ee10388'	System	29 Sep 2020 22:34:59
User entered '29 Sep 2020 17:34'	System	29 Sep 2020 22:34:59

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:48', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '6d7f1f4c-307f-4e35-aecf-ff804e693e72'	System	30 Sep 2020 17:10:53
User entered 'None (0)'	System	30 Sep 2020 17:10:53

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '6d7f1f4c-307f-4e35-aecf-ff804e693e72'	System	30 Sep 2020 17:10:53
User entered '30 Sep 2020 12:10'	System	30 Sep 2020 17:10:53

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:02', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd65e3d3d-9d56-4ddc-b47f-e229dceb76c2'	System	29 Sep 2020 22:35:11
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:09', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'd65e3d3d-9d56-4ddc-b47f-e229dceb76c2'	System	29 Sep 2020 22:35:11
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:10:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a42ae5f9-c607-4efb-a49c-2f659eb5c2ab'	System	30 Sep 2020 17:11:11
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:07', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a42ae5f9-c607-4efb-a49c-2f659eb5c2ab'	System	30 Sep 2020 17:11:11
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 22:35:11
User entered 'Day 10'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:10:55', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '141c4fb4-c7ae-4944-aaab-1b88dbd8acb9'	System	01 Oct 2020 20:11:04
User entered 'Some interference with activity (2)'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:10:58', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '141c4fb4-c7ae-4944-aaab-1b88dbd8acb9'	System	01 Oct 2020 20:11:04
User entered '01 Oct 2020 15:10'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:35:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:11:11
User entered 'Day 11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:35:56', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eda62ece-1454-46c0-9e4c-ae14c402cc26'	System	02 Oct 2020 17:36:09
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'eda62ece-1454-46c0-9e4c-ae14c402cc26'	System	02 Oct 2020 17:36:09
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 20:11:04
User entered 'Day 12'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:36:09
User entered 'Day 13'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:32', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '98aff5dd-e55b-4dba-a870-4a1ea51063a2'	System	04 Oct 2020 21:45:41
User entered 'No interference with activity (1)'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '98aff5dd-e55b-4dba-a870-4a1ea51063a2'	System	04 Oct 2020 21:45:41
User entered '04 Oct 2020 16:45'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 14'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 15'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:44:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '249b42b2-20c0-4459-bd83-e6e6ecd2a076'	System	06 Oct 2020 21:45:07
User entered 'Some interference with activity (2)'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:01', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '249b42b2-20c0-4459-bd83-e6e6ecd2a076'	System	06 Oct 2020 21:45:07
User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 16'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-07T17:15:25', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9c030b90-ebbe-49ce-bd22-1bd7596c2143'	System	07 Oct 2020 22:15:31
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-07T17:15:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '9c030b90-ebbe-49ce-bd22-1bd7596c2143'	System	07 Oct 2020 22:15:31
User entered '07 Oct 2020 17:15'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 17'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '59d7c286-6ecf-4893-a895-0405883ac43e'	System	08 Oct 2020 17:35:23
User entered 'No interference with activity (1)'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '59d7c286-6ecf-4893-a895-0405883ac43e'	System	08 Oct 2020 17:35:23
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 22:15:31
User entered 'Day 18'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:33:50', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '647c2d38-11bd-441e-8686-e3eabf371887'	System	09 Oct 2020 17:34:00
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:34:00

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:33:53', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '647c2d38-11bd-441e-8686-e3eabf371887'	System	09 Oct 2020 17:34:00
User entered '09 Oct 2020 12:33'	System	09 Oct 2020 17:34:00

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:35:23
User entered 'Day 19'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:30', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a178de0e-e7f6-4bb5-9ed2-3fb57d05a2fb'	System	10 Oct 2020 17:00:42
User entered 'None (0)'	System	10 Oct 2020 17:00:42

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:33', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'a178de0e-e7f6-4bb5-9ed2-3fb57d05a2fb' User entered '10 Oct 2020 12:00'	System	10 Oct 2020 17:00:42

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 17:35:49
User entered 'Day 8'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7a5737b4-3f3b-40a0-b219-ada6f0d13574'	System	29 Sep 2020 22:35:20
User entered 'No interference with activity (1)'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:35:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7a5737b4-3f3b-40a0-b219-ada6f0d13574'	System	29 Sep 2020 22:35:20
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:49
User entered 'Day 9'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:15', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0770885-b463-474b-8082-3a3abc49ac6d'	System	30 Sep 2020 17:11:26
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:49

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0770885-b463-474b-8082-3a3abc49ac6d'	System	30 Sep 2020 17:11:26
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 22:35:20
User entered 'Day 10'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:03', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '690ad48b-3bf8-4176-9b3e-d2a664cd26d9'	System	01 Oct 2020 20:11:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:35:20

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '690ad48b-3bf8-4176-9b3e-d2a664cd26d9'	System	01 Oct 2020 20:11:09
User entered '01 Oct 2020 15:11'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:11:26
User entered 'Day 11'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:07', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '69ef85fe-a0fd-4626-9235-f18a8bba1701'	System	02 Oct 2020 17:36:15
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:26

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:11', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '69ef85fe-a0fd-4626-9235-f18a8bba1701'	System	02 Oct 2020 17:36:15
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 20:11:09
User entered 'Day 12'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:09

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:36:15
User entered 'Day 13'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:49', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'db045ebe-eb99-4afa-914c-df4cd8db3846'	System	04 Oct 2020 21:45:56
User entered 'No interference with activity (1)'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:15

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:51', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'db045ebe-eb99-4afa-914c-df4cd8db3846'	System	04 Oct 2020 21:45:56
User entered '04 Oct 2020 16:45'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:56
User entered 'Day 14'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:56
User entered 'Day 15'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '54e8a2ef-c068-4bfd-989a-d5c61fe17cf3'	System	06 Oct 2020 21:45:14
User entered 'None (0)'	System	06 Oct 2020 21:45:14

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:56

US3492237

Folder: Diary Dose 1 (1)

Form: Chills_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:08', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '54e8a2ef-c068-4bfd-989a-d5c61fe17cf3'	System	06 Oct 2020 21:45:14
User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:14

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 17:33:05
User entered 'Day 8'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:25', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '32885fda-990c-452a-a73a-247ec252f7ac'	System	29 Sep 2020 22:35:33
User entered 'No (N)'	System	29 Sep 2020 22:35:33

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-29T17:35:27', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '32885fda-990c-452a-a73a-247ec252f7ac'	System	29 Sep 2020 22:35:33
User entered '29 Sep 2020 17:35'	System	29 Sep 2020 22:35:33

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:33:05

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:14:31
User entered 'Day 9'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4d9161e0-d81a-44b8-b445-2b698d1f5a50'	System	30 Sep 2020 17:11:34
User entered 'No (N)'	System	30 Sep 2020 17:11:34

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-09-30T12:11:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4d9161e0-d81a-44b8-b445-2b698d1f5a50'	System	30 Sep 2020 17:11:34
User entered '30 Sep 2020 12:11'	System	30 Sep 2020 17:11:34

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:14:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 22:33:54
User entered 'Day 10'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:16', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7127d8ad-8198-415c-904b-6957742ea226'	System	01 Oct 2020 20:11:27
User entered 'No (N)'	System	01 Oct 2020 20:11:27

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-01T15:11:22', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '7127d8ad-8198-415c-904b-6957742ea226'	System	01 Oct 2020 20:11:27
User entered '01 Oct 2020 15:11'	System	01 Oct 2020 20:11:27

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:33:54

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:11:11
User entered 'Day 11'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '08f07d7a-6efa-4c01-bbae-1da74fd88e17'	System	02 Oct 2020 17:36:25
User entered 'No (N)'	System	02 Oct 2020 17:36:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-02T12:36:20', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '08f07d7a-6efa-4c01-bbae-1da74fd88e17'	System	02 Oct 2020 17:36:25
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:36:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:11:11

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 20:11:04
User entered 'Day 12'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:11:04

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:36:09
User entered 'Day 13'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:45:57', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0c3dbb2-8809-49dd-ab8c-b2777e60e21c'	System	04 Oct 2020 21:46:06
User entered 'No (N)'	System	04 Oct 2020 21:46:06

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-04T16:46:00', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: 'c0c3dbb2-8809-49dd-ab8c-b2777e60e21c'	System	04 Oct 2020 21:46:06
User entered '04 Oct 2020 16:46'	System	04 Oct 2020 21:46:06

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:36:09

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 14'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 21:45:41
User entered 'Day 15'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '56217953-3ba0-4760-8c87-905a510973d7'	System	06 Oct 2020 21:45:25
User entered 'No (N)'	System	06 Oct 2020 21:45:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-06T16:45:17', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '56217953-3ba0-4760-8c87-905a510973d7'	System	06 Oct 2020 21:45:25
User entered '06 Oct 2020 16:45'	System	06 Oct 2020 21:45:25

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 21:45:41

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 21:45:07
User entered 'Day 17'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:26', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '3b9d0d1c-981d-4463-aa3f-61b9e8061a1b'	System	08 Oct 2020 17:35:31
User entered 'No (N)'	System	08 Oct 2020 17:35:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-08T12:35:28', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '3b9d0d1c-981d-4463-aa3f-61b9e8061a1b'	System	08 Oct 2020 17:35:31
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 17:35:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:45:07

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 22:15:31
User entered 'Day 18'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:34:06', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89f6fea5-02e5-48b2-8fe6-acfcf33ba315'	System	09 Oct 2020 17:34:16
User entered 'No (N)'	System	09 Oct 2020 17:34:16

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-09T12:34:14', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '89f6fea5-02e5-48b2-8fe6-acfcf33ba315'	System	09 Oct 2020 17:34:16
User entered '09 Oct 2020 12:34'	System	09 Oct 2020 17:34:16

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:15:31

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:35:23
User entered 'Day 19'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:37', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4b7854ca-7deb-4d92-9050-d292fe6271f0'	System	10 Oct 2020 17:00:47
User entered 'No (N)'	System	10 Oct 2020 17:00:47

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db52a8948cfd1968)', Time: '2020-10-10T12:00:39', User OID: 'PatientReportedOutcome (US3492237)', ODM File OID: '4b7854ca-7deb-4d92-9050-d292fe6271f0'	System	10 Oct 2020 17:00:47
User entered '10 Oct 2020 12:00'	System	10 Oct 2020 17:00:47

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:35:23

US3492237

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:30:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:35:23

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 17:29:58

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 17:30:03

US3492237

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 17:30:03

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25
	(b) (4)	

US3492237

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'diagnosed with SARS-CoV2 on 28Sep2020, in illness track'	Andrea Wendrow (b) (4)	12 Oct 2020 05:13:25

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	12 Oct 2020 05:13:35
	(b) (4)	

US3492237

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 05:13:35

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:43:45

US3492237

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:43:45

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	06 Nov 2020 15:06:24

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:10:48
Query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	06 Nov 2020 15:08:35
User opened query 'Per CDM: Visit Page for Visit 2 Day 29 has not been completed. Please complete the Visit Date page and provide a YES or NO response to 'Was this visit performed?.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:15:05
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:00

US3492237

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:44:00

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:10

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:44:32

US3492237

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:44:32

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:21:27

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:21:33

US3492237

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 18:21:33

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:30:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:29:50

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:29:57

US3492237

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:29:57

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Nov 2020 21:03:31

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:55'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:55'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 04:08:43
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Lorna Sanchez McCann	23 Nov 2020 21:08:10
answered with 'ncs' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Nov 2020 21:08:00
User entered '96.5' F	Lorna Sanchez McCann	23 Nov 2020 21:08:00
	(b) (4)	

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '125'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 21:08:00

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:30

US3492237

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:30

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:05'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 15:05'	System	23 Nov 2020 21:08:24

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	23 Nov 2020 21:08:33

US3492237

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:30:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:08:33

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 10:18:35

US3492237

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:30:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:18:35
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 10:18:35

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered '27 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered '28 Sep 2020'	Diana Bahena (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered '12:00' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered '11:13'	Diana Bahena (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	30 Sep 2020 15:30:17
User entered '28 Sep 2020 11:13'	System	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Sep 2020 15:30:17
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Diana Bahena (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:30:15

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:05
User entered 'Yes (Y)'	Diana Bahena (b) (4)	28 Sep 2020 19:03:04

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Diana Bahena (b) (4) (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:15:48
User entered '28 Sep 2020'	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:15:48
User entered '0'	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered '98'	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:17:00
User entered '%'	System	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered '100.5' F	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:17:00
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	28 Sep 2020 19:06:32
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:04:29

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '25 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:09

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '26 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:19:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '27 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:20:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '100.5' F	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:36:11

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '29 Sep 2020'	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '96'	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '100.0' F	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:55:17
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:53:38

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:11:58

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Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '01 Oct 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '95'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 21:11:58

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '97.5' F	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:11:58
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:12:08
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:11:58

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:14:24

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '02 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
User entered '02 Sep 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '99' F	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:14:24
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '05 Oct 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 21:24:53

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98' F	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	05 Oct 2020 21:24:53

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Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:15

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '30 Sep 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 21:25:15

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:15
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:25:56

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '03 Oct 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Diana Bahena (b) (4) (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '04 Oct 2020'	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1'	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	05 Oct 2020 21:26:29
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:03:01

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Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '06 Oct 2020'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:03:01

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Moderate (Moderate)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Not Done (Not Done)'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change:	Diana Bahena (b) (4)	12 Oct 2020 20:03:25
Data Entry Error	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:03:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 20:03:25
User entered '07 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	12 Oct 2020 20:03:25
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:03:01
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '1' reason for change: Data Entry Error	Diana Bahena (b) (4)	12 Oct 2020 20:03:25
User entered '0'	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered empty.	Diana Bahena (b) (4)	12 Oct 2020 20:03:01
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '08 Oct 2020'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:05:02

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '98.2' F	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:05:02
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Diana Bahena (b) (4) (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:40:08
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' answered with 'no this is correct' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:57:43
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:43:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '09 Oct 2020'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '0'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '99'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered '97.5' F	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'Mild (Mild)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:30:15

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:14
User entered 'None (None)'	Diana Bahena (b) (4)	12 Oct 2020 20:07:03
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:30:15

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered '28 Sep 2020'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41
	(b) (4)	

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Form: COVID Diagnostic Test

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[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'Yes (Y)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:30:15

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 12:15:03
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed' (Site from System).	Andrea Wendrow (b) (4)	01 Oct 2020 20:09:26
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	01 Oct 2020 20:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:09:12
User entered 'No (N)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41

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Folder: Covid-19 Assessment 27 Sep 2020

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[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered '22 Sep 2020'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:08:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered 'No (N)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:41

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:08:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:20
User entered empty.	Diana Bahena (b) (4)	28 Sep 2020 19:08:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:09:12
User entered '0'	System	28 Sep 2020 19:08:41

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

US3492237

Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Folder: Covid-19 Assessment 27 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Generated On: 26 Nov 2020 09:30:15

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Generated On: 26 Nov 2020 09:30:15

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56
	(b) (4)	

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:30:15

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:24
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:14:56

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Folder: Covid-19 Assessment 27 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:30:15

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:35
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:53:05
User entered 'Yes (Y)'	Diana Bahena (b) (4)	28 Sep 2020 19:08:52

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26
	(b) (4)	

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '30 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26
	(b) (4)	

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26
	(b) (4)	

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 21:52:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 21:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:52:25
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '2 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	02 Oct 2020 21:52:25
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26
	(b) (4)	

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:33:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:33:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '4 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:33:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:33:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '6 Oct 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	09 Oct 2020 23:33:34
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:45:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '11 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:45:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User entered '18 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Oct 2020 14:45:46
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:30:15

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:30:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 20:57:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 20:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:12:26
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 20:57:20
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:57:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 20:57:09
User entered '26 Oct ' (non-conformant).	(b) (4), (b) (6)	26 Oct 2020 20:57:09
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:12:26

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 20:36:45
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered 'Home (Home)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '11:13'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:13'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
DataPoint set to visible.	(b) (4) System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
DataPoint set to visible.	(b) (4) System	01 Oct 2020 20:36:45

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '100.5' F	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '97'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '20'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '118'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:06
User entered '68'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:25
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:09:25

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:10
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:51

US3492237

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:10
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:09:51
	(b) (4)	

US3492237

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:16
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:10:07

US3492237

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:16
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 21:10:07
	(b) (4)	

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:30:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '15:10'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 15:10'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:56:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 20:56:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:54:35
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:54:35
DataPoint set to visible.	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:56:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 20:56:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 20:54:35
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:54:35
DataPoint set to visible.	System	26 Oct 2020 20:53:30

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '97.6' F	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Other (Other)'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered 'Tympanic'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '73'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '20'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '135'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:32
User entered '85'	(b) (4), (b) (6)	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 20:54:35

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:56:28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:50
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:56:28

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:56:38

US3492237

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:30:15

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:05:42
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:56:38

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 16:01:16
User closed query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:13
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:27
Query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' answered with 'per query resolution' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 03:59:15
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
User opened query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:44:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:17
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	02 Oct 2020 21:35:51

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:17
User entered '1'	Andrea Wendrow (b) (4)	02 Oct 2020 21:35:51

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:17
User entered '1'	Andrea Wendrow (b) (4)	02 Oct 2020 21:35:51
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
User entered '0' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 03:59:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:17
User entered '1'	Andrea Wendrow (b) (4)	02 Oct 2020 21:35:51

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:30:15

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:17
User entered '0'	Andrea Wendrow (b) (4)	02 Oct 2020 21:35:51
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 16:01:23
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 04:00:39
	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered 'Yes (Y)'	(b) (4)	
	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '11:13'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:00:39
User entered '28 Sep 2020 11:13'	System	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '100.5' F	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered 'Oral (Oral)'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered empty.	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '97'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:00:39
User entered 'bpm'	System	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '20'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:00:39
User entered 'breaths/min'	System	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '118'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:00:39
User entered 'mmHg'	System	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:00:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:23
User entered '68'	Andrea Wendrow (b) (4)	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:30:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:00:39
User entered 'mmHg'	System	02 Oct 2020 21:50:56

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 16:01:26
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 04:01:08
	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:08
User entered empty; reason for change Per Query Resolution	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:08
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:06:27
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	02 Oct 2020 21:51:11
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:30:15

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:08
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:27
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	02 Oct 2020 21:51:11
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 16:01:30
Query 'Data is required. Please complete.' answered with 'per query resolution' (Site from System).	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	11 Nov 2020 04:01:38
	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
User entered empty; reason for change Per Query Resolution	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:06:31
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	02 Oct 2020 21:51:45
	(b) (4)	

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:31
User entered '28 Sep 2020'	Andrea Wendrow (b) (4)	02 Oct 2020 21:51:45

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	11 Nov 2020 04:01:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:31
User entered '11:27'	Andrea Wendrow (b) (4)	02 Oct 2020 21:51:45

US3492237

Folder: Unscheduled 28 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:30:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 04:01:38
User entered '28 Sep 2020 11:27'	System	02 Oct 2020 21:51:45

US3492237

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:30:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:01
User entered 'Yes (Y)'	Richard Novak (b) (4) (b) (4)	28 Sep 2020 21:15:01

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:07
User entered 'USA-US101-2020-mRNA-1273-P301000002'	System	02 Oct 2020 12:21:58
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 12:21:58

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:24
Query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' answered with 'confirmed' (Site from DM).	Andrea Wendrow (b) (4)	05 Nov 2020 21:12:14
User opened query 'Per MM, Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:28:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:27:49
Data point term sent to Coder	System	01 Oct 2020 20:26:12
User entered 'covid-19 infection'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:56:15
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:31:13
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:30:58
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:49:36
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '22 Sep 2020'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '14:00'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:00'	System	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:42
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:56
User entered '9 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:52:56
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 15:56:26
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Nov 2020 21:34:42
User entered empty.	System	01 Nov 2020 21:34:42
	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

US3492237

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:37
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 15:56:39
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'is SAE-Covid 19 iinfection' (Site from System).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:37
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:25
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	01 Nov 2020 21:34:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:42
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:35
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 03:14:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 03:12:52
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:41:06
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' answered with 'took tylenol for fever, naproxen for mylagias and body aches associated with COVID infection' (Site from DM).	Andrea Wendrow (b) (4)	18 Nov 2020 23:07:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:08:53
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:18:56
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'CM taken for symptoms of this AE, as recorded in CM log.' (Site from DM).	Diana Bahena (b) (4)	09 Nov 2020 17:31:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:58:53
User closed query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:44:20
Query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' answered with 'changed to fever' (Site from DM).	Andrea Wendrow (b) (4)	06 Nov 2020 03:17:39
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:14:42
User entered '0' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:12:52
User opened query 'Per CDM re-query: Previous response states 'corrected', however the medication still has the same indication recorded. Please review and update or clarify what was updated.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is "TREAT FEVER". Please review and reconcile AE term and CM indication, so there will be an appropriate match. Review and update eCRF as appropriate.' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4)	30 Oct 2020 07:48:53
	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered '0'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:59:49
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	01 Nov 2020 21:35:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Nov 2020 21:34:42
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:53:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
User entered empty.	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:39:31
Query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' answered with 'COVID positive on 9/22' (Site from DM).	Andrea Wendrow (b) (4)	18 Nov 2020 23:01:35
User opened query 'Per DM CLR: SAE Narrative = WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. Please review and confirm if this is the start date of this AE. If yes, please reconcile data with the AE start date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:09:17
User closed query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:25:21
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:25:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:28
Query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' answered with 'subject does not recall start dates but has been taking since prior to start of study' (Site from Safety).	Andrea Wendrow (b) (4)	06 Nov 2020 03:23:13
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'please clarify what you are asking for? Subject has asthma but not considered moderate by clinician' (Site from Safety).	Andrea Wendrow (b) (4)	06 Nov 2020 03:22:22
User opened query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 20:13:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 20:13:35
User closed query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:27
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:24
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:19
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 00:00:15
User closed query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:04:55
Query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:48:46
Query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:48:39
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:37
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 01 Nov 2020 21:36:08
User opened query 'Per DM CLR: SAE Narrative = PATIENT HAS ASTHMA. However, this is not recorded in the MH eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:49:27
User opened query 'PV Query: Please provide the start date for the following concomitant medications: Advair, Montelukast, fluticasone and azelastine.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:20
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:11
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:54:05
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:53:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CALLED study staff on 27Sep2020TO REPORT THAT HE HAS BEEN HAVING SYMPTOMS OF A RESPIRATORY INFECTION. HE RECEIVED HIS FIRST DOSE OF IP ON 9/22, WAS FINE UNTIL 9/24 WHEN HE REPORTS CHILLS AND FELT FEVERISH. HIS TEMP THAT DAY WAS ABOUT 99. THE FOLLOWING DAY HE DEVELOPED HEADACHE, CONTINUED WITH FEVER TO 101 AND CHILLS. YESTERDAY 9/26, HE DEVELOPED A PRODUCTIVE COUGH, SCANTY CLEAR SPUTUM. HE HAS BEEN TAKING NAPROSYN DAILY SINCE THE FEVERS BEGAN WITH SOME RELIEF. NO LOCALIZED INJECTION SITE PAIN. NO SOB. HE HAS ASTHMA AND CONTINUES TO USE HIS INHALER. NO KNOWN SICK CONTACTS ALTHOUGH HE REPORTS HIS WIFE IS HAVING A FLARE OF FIBROMYALGIA AND HAS A LOW GRADE FEVER.' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 21:59:42
User entered 'Participant called to report that he has been having symptoms of a respiratory infection. He received his first dose of IP on 9/22, was fine until 9/24 when he reports chills and felt feverish. His temp that day was about 99. The following day he developed headache, continued with fever to 101 and chills. Yesterday 9/26, he developed a productive cough, scanty clear sputum. He has been taking naprosyn daily since the fevers began with some relief. No localized injection site pain. No SOB. He has asthma and continues to use his inhaler. No known sick contacts although he reports his wife is having a flare of fibromyalgia and has a low grade fever.'	Andrea Wendrow (b) (4)	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:30:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 20:25:32

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:25:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:30:15

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:11:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:13:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:13:47
Data point term sent to Coder	System	22 Sep 2020 21:12:47
User entered 'advair'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:15
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:45:05
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 01:37:05
User entered 'asthma'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '500-50'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:17
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:46:40
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	01 Nov 2020 21:46:29
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 01:37:45
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:12:08

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:17:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:17:53
Data point term sent to Coder	System	22 Sep 2020 21:16:54
User entered 'montelukast'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'asthma'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '10'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:16:17

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:18:39
Data point term sent to Coder	System	22 Sep 2020 21:17:55
User entered 'fluticasone'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:39
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:46:57
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:11:46
User entered 'allergic rhinitis'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '100'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:14:28
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'QUERY RESOLVED' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	07 Oct 2020 15:12:41
User entered 'ug (ug)' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4) (b) (4)	07 Oct 2020 15:12:29
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:52:55
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty; reason for change Per Query Resolution	Gizelle Alvarez (b) (4)	07 Oct 2020 15:12:29
User entered 'mcg'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:17:14

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
Data point term sent to Coder	System	22 Sep 2020 21:18:59
User entered 'azelastine'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:46:03
User entered 'allergic rhinitis'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:49
Query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:32
User entered '2' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:24
User opened query 'Per DM CLR: Please review and remove the units (SPRAY) in the Dose field as this should only be captured in the 'Dose Unit' field. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:46:16
User entered '2 spray'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'puff (PUFF)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:18:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 21:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:18:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:18:00

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:10:49
Data point term sent to Coder Coding entries removed.	System Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:09:43 18 Nov 2020 23:09:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	06 Nov 2020 17:07:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:10:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:10:51
Data point term sent to Coder User entered 'TYLENOL'	System (b) (4), (b) (6) (b) (4)	28 Sep 2020 18:09:52 28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:07
User entered 'FEVER associated with COVID infection' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:07
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'FEVER'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '500'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Sep 2020 18:09:32
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:09:32
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Sep 2020 18:08:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
DataPoint Un-verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
User entered '01 Oct 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	Andrea Wendrow (b) (4)	18 Nov 2020 23:05:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 18:09:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 18:09:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Sep 2020 18:09:32
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 18:08:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:08:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:19:41
Data point term sent to Coder	System	22 Sep 2020 21:19:00
User entered 'pantoprazole'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:08:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	01 Nov 2020 21:47:46
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:57:17
User entered 'gerd'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '40'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '01 Jan 2018'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 21:18:58

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:50:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:50:00
Data point term sent to Coder Coding entries removed.	System Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:09:43 18 Nov 2020 23:09:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:46:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:46:39
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:27:37 09 Nov 2020 17:26:42
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 03:18:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 03:18:28
Data point term sent to Coder	System	06 Nov 2020 03:17:29

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Andrea Wendrow (b) (4)	06 Nov 2020 03:17:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 23:12:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 23:12:56
Data point term sent to Coder	System	01 Oct 2020 20:27:13
Coding entries removed.	Andrea Wendrow (b) (4)	01 Oct 2020 20:26:39
User entered 'NAPROXEN' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:26:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN, PRODUCTSYNONYM: NAPROXENE [NAPROXEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:36:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:36:48
Data point term sent to Coder	System	28 Sep 2020 18:10:56
User entered 'Naproxene'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'MYALGIAS, ARTHRALGIAS associated with covid infection' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	18 Nov 2020 23:09:42
DataPoint Un-verified.	Diana Bahena (b) (4)	09 Nov 2020 17:26:42
User entered 'Myalgias, arthralgias' reason for change: Data Entry Error	Diana Bahena (b) (4)	09 Nov 2020 17:26:42
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'FEVER' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	06 Nov 2020 03:17:23
User entered 'treat fever'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '220'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '24 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	01 Oct 2020 20:26:39
User entered '27 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:19:41
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' ' answered with 'reviewed and updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 17:26:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:40
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 3 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, and update this field to No. Else, provide clarification.' ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:38:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 20:26:39
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:10:49

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:42:54
Data point term sent to Coder	System	18 Nov 2020 16:37:19
User entered '2nd Dose of Shingles Vaccine'	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Prophylaxis'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'UNK'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Other (OTHER)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'UNK'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'once (ONCE)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Intramuscular (INTRAMUSCULAR)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '10 Nov 2020'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '0'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '10 Nov 2020'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Nusirat Williams (b) (4)	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:37:18
DataPoint activated with code reason code Data required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	01 Oct 2020 21:13:33

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:15:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:15:53
Data point term sent to Coder	System	18 Nov 2020 23:14:47
User entered 'azithromycin'	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4) (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'cough from COVID'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '250'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'mg (mg)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'once daily (QD)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered empty.	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '05 Oct 2020'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '0'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered '09 Oct 2020'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:57:29
User entered 'No (N)'	Andrea Wendrow (b) (4)	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:30:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 23:14:28
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	18 Nov 2020 23:13:25
DataPoint inactivated with code reason code Data not required.	Nusirat Williams (b) (4)	18 Nov 2020 16:35:39

US3492237

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:30:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 21:28:43

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:30:15

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:30:15

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Andrea Wendrow (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:30:15

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	12 Oct 2020 05:11:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:30:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered '02/Oct/2020 12:22'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:30:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:30:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered '03/Nov/2020 00:00'	System	03 Nov 2020 00:00:53

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:30:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:25:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 00:00:53

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:32
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:28
User entered 'USA-US101-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'No (N)'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Richard'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Novak'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '808 S. Wood St'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'Chicago'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered 'IL'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:22:35
User entered '60612'	System	02 Oct 2020 12:21:58

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 00:00:41
User entered 'US'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:30:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Nov 2020 18:26:23
User entered '2'	System	03 Nov 2020 00:00:53
User entered '1'	System	02 Oct 2020 12:22:42

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:30:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 13:26'	System	09 Nov 2020 18:26:23

US3492237

Folder: SAE USA-US101-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:30:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 18:26:23